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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,519	03/20/2006	Inge Dorthe Hansen	HOI-14302/16	5664

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,519	HANSEN, INGE DORTHE	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 05/07/08.

The amendment filed 05/07/08 affects the application, 10/560,519 as follows:

1. Claims 30, 31, 35 and 53 have been amended. New Claims 56-61 have been added. Applicant's amendments have overcome the rejections made under 35 U.S.C. 112, second paragraph and first paragraph, and under 35 U.S.C. 102 in the office action mailed 01/08/08. However, a new ground(s) rejection is set forth herein below.
2. The responsive to applicants' arguments is contained herein below.

Claims 30-61 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30, 53 and 58 are indefinite because, it is unclear whether or not a gel or suspension that comprises at least 75% by weight of said saccharide (as recited in b)) is not considered a medicament which comprises at least 75% by weight of said saccharide (as recited in a)) .

Claim 36 recites the phrase "wherein the medicament comprises at least 25 percent by weight of the saccharide". However, the claim is indefinite since the percent by weight of the saccharide must be at least 40% by weight as recited in claim 30 on which claim 36 depends.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of bacterial vaginosis in an individual, does not reasonably provide enablement for the prophylaxis or prevention of bacterial vaginosis or one or more symptoms associated with bacterial vaginosis in said individual. Claim 58 is drawn to a method for prophylaxis of bacterial vaginosis or one or more symptoms associated with bacterial vaginosis, comprising administering to an individual in need an effective amount of a medicament comprising a saccharide, the medicament including less than 10^5 bacteria per dosage, and

a) wherein the medicament comprises at least 75 percent by weight of said saccharide or b) wherein the medicament is a gel or suspension comprising at least 40 % by weight of said saccharide.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to

consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains a method for prophylaxis of bacterial vaginosis or one or more symptoms associated with bacterial vaginosis, comprising administering to an individual in need an effective amount of a medicament comprising a saccharide, the medicament including less than 10^5 bacteria per dosage, and a) wherein the medicament comprises at least 75 percent by weight of said saccharide or b) wherein the medicament is a gel or suspension comprising at least 40 % by weight of said saccharide.

The relative skill of those in the art: The relative skill of those in the art is high. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on preventing bacterial vaginosis in a comprising administering to any individual an effective amount of a given composition.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18

(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses preventing bacterial vaginosis and the recurrence of bacterial vaginosis in an individual by administering the said composition to an individual, which are not known to have a single recognized cause. Applicant claims method of preventing bacterial vaginosis in an individual, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said bacterial vaginosis, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the said disease is not known to have a single recognized cause. Moreover, the exact cause of bacterial vaginosis is unknown (see Schwebke et al., page 62, 1st col., last paragraph). Furthermore, most women with bacterial vaginosis do not have any symptoms. In fact, the aforementioned disease, is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which includes (1) personal hygiene (2) change in the normal bacteria of the vagina (3) douching (4) using an intrauterine device (IUD) for birth control (5) using too many perfumed soaps or bubble baths. These are only a few of the factors that promote these diseases in people. It is important to note that bacterial vaginosis reoccurs in some women and since it is unclear why or how these recurrences or relapses occur, it not possible to predict the time of such reoccurrence so as to attempt to provide any preventative methods of treatment. Applicant has not provided a description as to how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be

prevented. Furthermore, Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed methods with a reasonable expectation of success. Therefore, the prevention of the said disease in a patient or individual is not enabled by the instant disclosure.

Thus, the skilled artisan would view that the prevention of bacterial vaginosis or the prevention of its recurrence (which is characterized as having many contributing factors and causes) in a woman or individual by administering to said woman or individual the specific composition or medicament herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

Moreover, it is noted that the specification provides no working examples as to how bacterial vaginosis or the recurrence of bacterial vaginosis can be prevented.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of bacterial vaginosis in an individual as recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of preventing bacterial vaginosis in any individual or woman as recited in the instant claims suitable

to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, the prevention of the bacterial vaginosis in an individual or woman by the said method is not enabled by the instant disclosure.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woitun et al. (DE 1959402 A) (English Translation by Machine).

Claim 53 is drawn to a pharmaceutical composition for vaginal application, comprising a saccharide, the composition including less than 10^5 bacteria per dosage, and

a) wherein said saccharide constitutes at least 75 percent by weight of said pharmaceutical composition or b) wherein the pharmaceutical composition is a gel or suspension and said saccharide constitutes at least 40 % by weight of said pharmaceutical composition. Claim 54 is drawn to a kit comprising the pharmaceutical composition of claim 53 and an anti-fungal and/or an anti-bacterial agent for simultaneous, sequential or separate use. Claim 55 is drawn to a kit-of-parts comprising the pharmaceutical composition as defined in claim 53 and at least one pH measurement means, for measuring vaginal pH. Claim 56 is drawn to the pharmaceutical composition according to claim 53, wherein the composition further includes an effective amount of an anfi-fungal agent or an anti-bacterial agent. Claim 57 is drawn to the pharmaceutical composition according to claim 53, wherein said saccharide is the essential active component.

Woitun et al. disclose applicant's composition for vaginal use comprising a saccharide (lactose) (see abstract and examples). Woitun et al.'s composition also contains an antifungal/antibacterial agent (see abstract and examples). It should be noted that the kit does not add to the patentability of the composition claimed.

The difference between applicant's claimed composition and the composition of Woitun et al. is the percent or amount of saccharide and bacteria in the composition. However, it is obvious to prepare Woitun et al.'s composition in different percent or amounts of saccharide or bacteria based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Woitun et al.'s composition comprising different percent or

amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare Woitun et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should be noted that is obvious to combine compositions that have the same utility to treat the same condition or disorder (e.g. to further include or combine other anfi-fungal agent or an anti-bacterial agent with Woitun et al.'s composition in order to treat the same said condition). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). In addition, it should be noted Woitun et al.'s saccharide (which is the same as applicant's saccharide) should inherently have the same effect or property of being an active ingredient.

Claims 30-48, 51-52, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozmen et al. (Turkish journal of Medical Sciences (1998), 28 (2), pages 171-173).

In claim 30, applicant claims a method for the treatment and/or amelioration of one or more symptoms associated with bacterial vaginosis, comprising administering to an individual in need an effective amount of a medicament comprising a saccharide wherein the medicament includes less than 10^5 bacteria per dosage, and

a) wherein the medicament comprises at least 75 percent by weight of said saccharide or b) wherein the medicament is a gel or suspension comprising at least 40 % by weight of said saccharide. Claims 31-39 are drawn to said method involving specific symptoms, saccharides (including lactose) and composition comprising specific percentage by weight of saccharide. Claims 40-41 are drawn to said method wherein the bacterial vaginosis has specific cause. Claims 42 and 43 are drawn to said method involving specific forms of said composition. Claim 59 is drawn to a method of reducing vaginal pH to below 4.7, comprising administering to an individual in need an effective amount of a medicament comprising said saccharide. Claims 60-61 are drawn to the method of claim 59 wherein the vaginal pH is reduced to below 4.5 and further, wherein said vaginal pH is measured subsequent to said administering.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract, see also page 172, 1st col., 2nd paragraph and 2nd col., last paragraph). It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference.

The difference between applicant's claimed method and the method of Ozmen et al. is the percent or amount of saccharide in the composition. However, it is obvious to prepare and administer Ozmen et al.'s composition comprising different percent or amounts of saccharide and bacteria based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer Ozmen et al.'s composition comprising different percent or amounts of saccharide and bacteria, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare and administer Ozmen et al.'s composition comprising different percent or amounts of saccharide and bacteria, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should be noted that is obvious to combine compositions that have the same utility to treat the same condition or disorder (e.g. to further include or combine other anfi-fungal agent or an anti-bacterial agent with Ozmen et al.'s composition in order to treat the same said condition). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). In addition, it should be noted Ozmen et al.'s saccharide (which is the same as applicant's saccharide) should inherently have the same effect or property as being an active ingredient. Also, it should be noted that it is well known in the art that the normal pH of vaginal secretions is less than 4.5. In women with bacterial vaginosis, the pH is usually greater than 4.5. Thus, it is obvious to a skilled artisan that a treatment of bacterial vaginosis would be accompanied by a reduction or lowering of the vaginal pH and consequently a skilled artisan would be motivated to determine or monitor the said vaginal pH or change in vaginal pH upon treatment with Ozmen et al.'s composition so as to determine the extent of the said

treatment and also based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

Claims 44-46 are drawn to the method of claim 30, wherein the medicament is in the form of a vaginal capsule, tablet or suspension. Claims 47-48 are drawn to the method of claim 30, wherein the medicament is of specific dosage unit.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract, see also page 172, 1st col., 2nd paragraph and 2nd col., last paragraph). It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference.

The difference between applicant's claimed method and the method of Ozmen et al. is the form of the composition used. However, it is obvious to prepare Ozmen et al.'s composition in different forms such as capsule, tablet or suspension that are commonly used in the art based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer Ozmen et al.'s composition in different forms such as capsule, tablet or suspension that are commonly used in the art, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare and administer Ozmen et al.'s composition in different forms such as capsule, tablet or suspension that are commonly used in the art, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should also be noted that the preparation oral formulations of composition in forms such as tablets, capsules, suspensions, or liquid formulations are well within the purview of a skilled artisan. Also, it should also be noted that the use of specific dosage units depend on factors such as the type and severity of the symptom or condition and type, mass and age of individual treated.

Claims 51-52 are drawn to said method wherein the medicament or composition further includes an effective amount of antibacterial agent and specific antibacterial agent including metronidazole.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract, see also page 172, 1st col., 2nd paragraph and 2nd col., last paragraph). It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference. Furthermore, Ozmen et al. disclose that the antibacterial agent, metronidazole can be used to treat said symptoms of bacterial vaginosis (see abstract; see also page 172, 1st col., 2nd paragraph).

The difference between applicant's claimed method and the method of Ozmen et al. is the applicant composition further comprises an effective amount of antibacterial agent including

metronidazole. However, Ozmen et al. disclose that the antibacterial agent, metronidazole can be used to treat said symptoms of bacterial vaginosis (see abstract; see also page 172, 1st col., 2nd paragraph).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer a composition comprising a combination of saccharide (lactose) and the antibacterial, metronidazole taught by Ozmen et al. in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated to prepare and administer a composition comprising a combination of saccharide (lactose) and the antibacterial, metronidazole taught by Ozmen et al. in order to treat the symptoms associated with bacterial vaginosis, based of factors such as the type and severity of the symptom or condition and type and age of individual treated, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

Claims 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ozmen et al. (Turkish journal of Medical Sciences (1998), 28 (2), pages 171-173) in combination with Lin et al. (US 2003/0017207 A1).

Claims 49-50 are drawn to said method wherein the medicament or composition further includes an effective amount of antibacterial agent and specific antibacterial agent.

Ozmen et al. disclose applicants' method for the treatment of symptoms associated with bacterial vaginosis, comprising administering an effective amount of a medicament comprising a saccharide (lactose suppository) (see abstract). It should be noted that fermented lactose does not render applicant's lactose as been different from Ozmen et al.'s lactose since said fermented saccharide is still a saccharide as claimed by applicant with no chemical or structural difference. Furthermore, Ozmen et al. disclose that the antibacterial agent, metronidazole can be used to treat said symptoms of bacterial vaginosis (see abstract; see also page 172, 1st col., 2nd paragraph).

The difference between applicant's claimed method and the method of Ozmen et al. is the applicant composition further comprises an effective amount of antifungal agent.

Lin et al. disclose that the antifungal agents can be used to treat vaginosis (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared and administer a composition comprising a combination of Ozmen et al.'s saccharide (lactose) and an antifungal as taught by Lin et al. in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated to prepare and administer a composition comprising a combination of Ozmen et al.'s saccharide (lactose) and an antifungal as taught by Lin et al. in order to treat the symptoms associated with bacterial vaginosis, based

on factors such as the type and severity of the symptom or condition and type and age of individual treated.

Response to Arguments

Applicant's arguments with respect to claim 30-61 have been considered but are not found convincing.

The applicant argues that while the active component according to Ozmen is metronidazole, which is also mentioned in the application as filed (page 3, line 12), in the Ozmen et al. reference, lactose is provided as a substrate for the accompanying lactobacilli included in the Estriol composition Gynoflor. The lactose and lactobacilli are thus a functional unit. Therefore, it would not be obvious to one of ordinary skill in the art to omit or reduce either of the ingredients lactose or lactobacilli. Based on Ozmen, there would be no expectation of success by employing saccharide as active agent for treatment of vaginosis. Furthermore, as the claims are compositionally limited to the specific content of the bacteria mentioned above, the ordinarily skilled artisan could not even envision the compositions employed in the present inventive methods, let alone modifying the methods referred to by Ozmen et al. and arriving at the claimed methods with a reasonable expectation of success.

However, Ozmen et al uses the same saccharide (lactose) in their composition as applicant to treat the same condition in the same patient or individual as applicant. Thus, Ozmen et al.'s saccharide (lactose) should inherently have the same effect or property of being an active ingredient regardless or whether or not applicant considers lactose as being a substrate or functional unit with lactobacilli. It should be noted the applicant composition or medicament which comprises a saccharide does not exclude or active ingredients such as metronidazole. In

fact, applicant's method uses a composition which comprises or further includes anti-bacterial agent or active ingredients such as metronidazole and clindamycin (see applicant's claims 51-52). Consequently, Based on Ozmen, there would be expectation of success by employing saccharide as active agent for treatment of vaginosis. Furthermore, as set forth in the above rejection, one having ordinary skill in the art would have been motivated to prepare and administer Ozmen et al.'s composition comprising different percent or amounts of saccharide and bacteria, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

The applicant argues that Lin et al. refer to use of anti-fungal agents; however, Lin et al. do not provide any motivation to use saccharide compositions with less than 10^5 bacterial per dosage. Put another way, the deficiency of the primary reference of Ozmen et aI. with respect to the specific bacterial content of the claimed invention under consideration, is not removed by Lin et al.

However, as set forth in the above rejection, one having ordinary skill in the art would have been motivated to prepare and administer Ozmen et al.'s composition comprising different percent or amounts of saccharide and bacteria, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
August 14, 2008.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623